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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,594	09/07/2000	Milton F. Ferreira	3673-3	5221

7590

08/08/2002

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EXAMINER

LUDLOW, JAN M

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 08/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

72-11

Office Action Summary

Application No.

09/600,594

Applicant(s)

FERREIRA ET AL.

Examiner

Jan M. Ludlow

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 September 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Art Unit: 1743

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1743

5. Claims 1, 2, 4, 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Meucci et al.

Meucci teaches a method of testing for hydrophobic drugs in patient samples by precipitating with a mixture of zinc sulfate, alcohol and acid, centrifuging and analyzing the supernatant (col. 2, col. 3, lines 25-52).

1. Claims 3, 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meucci et al.

2. Meucci fails to teach the concentration or assays claimed.

3. With respect to claim 3, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a stronger concentration of zinc sulfate in a smaller added volume in order to provide the same concentration of zinc sulfate in the sample while minimizing sample dilution as was known in the art. With respect to claim 7, it would have been obvious to use ascorbic acid for its known acidic function. With respect to claim 8, it would have been obvious to use other known assay methods after the sample preparation as taught by Meucci. With respect to claims 9-10, it would have been obvious to use the sample preparation method on other hydrophobic drugs as taught by Meucci.

4. Claims 5, 11-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meucci et al as applied to claims 1-4, 6-10 above, and further in view of Lam et al.

Meucci fails to teach the claimed solvents.

Lam et al. teach a method of protein precipitation prior to testing similar to that of Meucci. Acetonitrile is used with methanol as the precipitating solvent.

Art Unit: 1743

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use acetonitrile in addition to the alcohol of Meucci in order to precipitate proteins with zinc sulfate as taught by Lam et al. With respect to the kit claims, it would have been obvious to package necessary reagents for treatment and assay as was known in the art.

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

6. Elsbach teaches that rifamipicin is hydrophobic.

7. Bergqvist additionally teaches zinc sulfate precipitation with acetonitrile.

8. Applicant's arguments filed June 21, 2002 have been fully considered but they are not persuasive.

9. Applicant argues on page 5 of the response that Meucci does not teach that the alcohol is a solvent, but this argument is specious at best. Alcohol is a solvent. It "participates in maintaining the ... analyte in solution", as acknowledged by applicant on the last line of page 4 of the response. Further, the claims do not require that the alcohol participate in extraction or solvation of any particular component, but merely that "an appropriate solvent" is added to the sample and zinc sulfate solution and applicant discloses that alcohols are "appropriate". Applicant argues that the instant invention does not use a glycol component, but the instant claims do not preclude the use of a glycol component ("... **comprising** the following..."). Note further that Lam and Bergqvist, of record, teach precipitation with zinc sulfate in an appropriate solvent without a glycol component. Applicant further argues that Meucci teaches that the

Art Unit: 1743

optional acid is used to precipitate and denature interfering proteins, but a) the instant claims do not preclude an acid, and in fact claim ascorbic acid, and b) since acid is an optional component of Meucci, it would have been obvious to omit it if applicant were to preclude the acid in the claims. With respect to the antioxidizing agent of the instant claims, it is OPTIONAL and therefore the prior art need not teach it in order to satisfy the claims. Additionally, acetic acid, as taught by Meucci is a natural antioxidant (see, e.g., Vadhar, col. 15, line 53) and ascorbic acid is "the like" (col. 2, line 67 of Meucci) of acetic acid in that they are both organic acids.

10. Applicant requests where in Meucci is the motivation to add a more concentrated solution in a smaller volume, but such is not taught in Meucci, but rather is obvious over Meucci based on fundamental mathematical and laboratory principles well known to one of ordinary skill in the art who is familiar with arithmetic equivalents, e.g., absent a showing of criticality, it would have been obvious to add, e.g., 1 ul of .2 M zinc sulfate instead of 2 ul of .1 M solution in order to deliver the same amount of zinc sulfate to the sample. Note that the claims are not directed to the concentration of zinc sulfate in the sample-containing solution, but rather to the concentration in the solution supplied.

With respect to the specified assays, Meucci teaches that the precipitation method is generally applicable to sample preparation for assays of hydrophobic analytes in biological fluids (col. 1, lines 50-65) and it therefore would have been obvious to use it for the claimed tests of hydrophobic analytes in biological fluids. Applicant argues that Meucci uses different components for different purposes than the instant invention, but

Art Unit: 1743

fails to point out any claim language that defines over the invention of Meucci and its obvious variations.

11. With respect to Lam, applicant argues that better detection levels are provided with the instant method, but fails to point out any claim language defining over the prior art which results in this improved detection. Applicant further argues that precipitation starts earlier in Lam because of the sequential addition of components, but points to no claim language defining over such serial addition. Applicant further argues that the instant method can be used on smaller samples and with more analytes, but points to no claim language specifying sample size or an analyte not encompassed by the broad teachings of Meucci and Lam.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 1743

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (703) 308-4039. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



Jan M. Ludlow
Primary Examiner
Art Unit 1743

jml
August 6, 2002